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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,570	01/23/2004	Pamela M. Drake	340082.401	4880

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EXAMINER	
BARNHART, LORA ELIZABETH	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,570	DRAKE ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8 and 11, drawn to a kit comprising bacteria, a bacterial nutrient, and an antimicrobial agent, classified in class 435, subclass 252.1.

II. Claim 9, drawn to a kit comprising *Bifodophilus infantis* and fructooligosaccharides, classified in class 435, subclass 252.1.

III. Claim 10, drawn to a kit comprising numerous bacteria and fructooligosaccharides, classified in class 435, subclass 252.1.

IV. Claims 12-19, drawn to a method of enhancing bacteria in a patient, classified in class 435, subclass 252.1.

V. Claim 22, drawn to a method of enhancing beneficial bacteria in a patient treated with chemotherapy, classified in class 435, subclass 252.1.

VI. Claim 23, drawn to a method of enhancing beneficial bacteria in a patient treated with radiation, classified in class 435, subclass 252.1.

VII. Claim 24, drawn to a method of introducing beneficial bacteria to a patient treated with an antibiotic, classified in class 435, subclass 252.1.

VIII. Claim25, drawn to a method of inhibiting or reducing infection in a patient, classified in class 435, subclass 252.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I-III are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

Group I specifically requires three components: bacteria, a nutrient, and an antimicrobial agent. Groups II and III require no antimicrobial agent and are therefore distinct from Group I. Groups II and III are distinct from each other because they comprise patentably distinct combinations of bacteria. In addition, the composition of Group II is required to be in powder form. Therefore, a search and examination of all three products in one patent application would result in an undue burden, since the searches for the products are not co-extensive, the classification is different, and the subject matter is divergent.

Groups IV-VIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Groups IV-VIII are drawn to five treatment methods that are appropriate for use on five distinct patient groups. Therefore, a search and examination of all five methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Invention I is related to Inventions IV-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Group I can be used in numerous distinct methods, for example the methods of Groups IV-VIII. Because these inventions are distinct for the reasons given above and the literature search required for Groups IV-VIII is not required for Group I, restriction for examination purposes as indicated is proper.

Inventions II and III are unrelated to Inventions IV-VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods of use and to products not required to perform said methods. Because these inventions are distinct for the reasons given above and the literature search required for Groups II and III is not required for Groups IV-VIII, and *vice versa*, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Bacterial compositions: (a) compositions comprising one bacterium, selected from a list, as in claim 3; (b) compositions comprising three specific bacteria, as in claim 6; (c) compositions comprising six specific bacteria, as in claim 7; and (d) compositions comprising eight specific bacteria, as in claim 8.

Bacteria within the composition of claim 3: (e) *Lactobacillus acidophilus,* (f) *Lactobacillus bulgaricus,* (g) *Streptococcus thermophilus,* (h) *Bifodophilus longum,* (i) *Bifidobacteria bifidus,* (j) *Bacillus laterosporus,* (k) *Bacillus bifidum,* (m) *Lactobacillus plantaterum,* (n) *Lactobacillus rueteri,* and (o) *Lactobacillus salivarius.*

Bacterial nutrients: (p) spirulina, (q) chlorophyllins, (r) fructooligosaccharides, and (s) methylsulfonylmethane.

Type of animal: (t) human and (u) non-human.

Additional treatments: (v) antibiotics, (w) radiation, (x) a hormone, (y) chemotherapy, (z) ulcer medication, (a') a steroid, or (b') a vaccine.

Diseases and conditions: (c') cancer, (d') acquired immunodeficiency disease, (e') autoimmune disorders, (f') food allergy, (g') lactose intolerance, (h') fatigue, (i') malnutrition, (j') neuropsychiatric symptoms, (k') inflammatory bowel disease, (m') ulcerative colitis, (n') diarrheal diseases, (o') diverticulitis, (p') ostomies, (q') ulcers, (r') high cholesterol, (s') chronic disease, (t') immunocompromization, (u') bacterial infection, (v') yeast infection, (w') viral infection, (x') fungal infection, (y') irritable bowel syndrome, (z') Krohn's disease, (a") periodontal disease, (b") chronic respiratory infection, (c") upper respiratory infection, (d") ear infection, (e") sinus infection, (f") necrotizing enterocolitis, (g") ileocecitis, (h") multiple organ failure syndrome, (j") pancreatitis, and (k") burn injury.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. That is, if Group I be elected, applicants should elect ONE composition from (a)-(d) above and ONE bacterial nutrient from (p)-(s) above. If species (a) be chosen, applicants should also elect ONE bacterium from (e)-(o) above. If Group IV be chosen, applicants should elect ONE type of animal from (t) and (u) above AND elect ONE additional treatment from (v)-(b') above. If Group IV and species (v) be elected, claim 22 will be rejoined to Group IV. If Group IV and species (w) be elected, claim 23 will be rejoined to Group IV. If Group IV and species (y) be elected, claim 24

will be rejoined to Group IV. if Group VIII be elected, applicants should elect ONE disease or condition from (c')-(k") above. Currently, claims 1-26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

with the provisions of M.P.E.P. § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35U.S.C. §§101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to maintain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the protection against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

leb

SANDRA E. SAUCIER
PRIMARY EXAMINER